DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2005

Ms. Yossi Shachar
QA/RA Manager
Migada Plant
P.O. Box 888
Kiryat Shmona 10258
ISRAEL

Re: K051669
Trade/Device Name: TEVADAPTOR™, Drug Reconstitution and Transfer System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: June 14, 2005
Received: June 22, 2005

Dear Ms. Shachar:

This letter corrects our substantially equivalent letter of September 1, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SEP - 1 2005

Medical Ltd.
migada

מדיקל בע"מ
מיגדה תעשיות ציוד רפואי

THE STANDARDS INSTITUTION OF ISRAEL

510(k) Summary:
TEVADAPTOR™, Drug Reconstitution and Transfer System

Company Name:
Migada Plant

Contact Person:
Yosi Shahar
QA/RA manager

Telephone: +972-4-690-8826
Fax: +972-9-892-1665
E-mail: yosi.shahar@teva.co.il

US Agent:
George Svokos
MIGADA, INC.
482 Hudson Terrace
Englewood Cliffs, NJ 07632

Phone: 201-561-1010
Fax: 201-567-7994

Date prepared: May 10, 2005

Trade Name:
TEVADAPTOR™, Drug Reconstitution and Transfer System

Classification name: Set, IV Fluid Transfer

A MEMBER OF TEVA GROUP

מקבוצת טבע

אזור התעשיה הצפוני ת.ד 888 קרית שמונה 10258 טלפון: 04-6908800 פקס: 09-8921665
NORTH IND. ZONE P.O.BOX 888 KIRYAT SHMONA 10258 ISRAEL TEL: (972)-4-6908800 FAX: (972)-9-8921665

TEVA Medical Ltd.
migada
מדיקל בע"מ
מיגדה תעשיות ציוד רפואי

Common/usual name: Drug reconstitution system

Product Code: LHI

Regulation No.: 880.5440

Class: II

Panel identification: General Hospital Panel

Predicate Device:
PhaSeal® closed system for the preparation and administration of parenteral drugs, Carmel Pharma AB, S-402 28 Gottingen, Sweden, cleared under 510(k) no. K980381.

Description of the device:
The device comprises of the following components:
- Vial Adaptor System with 13 mm Vial converter
- Syringe Adaptor System
- Infusion Bag Adaptor
- I Connector

The Vial Adaptor System is intended to fit over vials with 20mm caps. A converter accessory enables the use of the Vial Adaptor System with a 13 mm cap vial. A special venting mechanism ensures automatic, sterile, pressure equalization within the vial, preventing drug particle escape into the environment. An elastomeric, non-latex septum is designed for connection of the Syringe Adaptor System for introduction or withdrawal of liquid.

A MEMBER OF TEVA GROUP
מקבוצת
אזור התעשיה הצפוני ת.ד 888 קרית שמונה 10258 טלפון: 04-6908800 פקס: 09-8921665
NORTH IND. ZONE P.O.BOX 888 KIRYAT SHMONA 10258 ISRAEL TEL: (972)-4-6908800 FAX: (972)-9-8921665

TEVA Medical Ltd.
migada

CERTIFIED QMS ISO 13485:2003
THE STANDARDS INSTITUTION OF ISRAEL

טבע מדיקל בע"מ
מיגדה תעשיות ציוד רפואי

The Syringe Adaptor System is intended for connection to a standard luer lock syringe. A special non-latex elastomer protector covers the liquid dispensing needle tip. A clamp mechanism reversibly connects the Syringe Adaptor System to the other components.

The Infusion Bag Adaptor is intended for connection to the spike port of an infusion bag. A non- latex septum enables connection to the Syringe Adaptor System for withdrawal of diluents or introduction of drug. A capped short tubing enables connection of the drug containing bag to a delivery set in the hospital ward.

An injection accessory enables the connection of the Syringe Adaptor System to an intravenous infusion line for direct drug injection.

Indications for Use:
The TEVADAPTOR™, Drug Reconstitution and Transfer System is a contained system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs, for intravenous infusion or injection.

Substantial Equivalence:
The TEVADAPTOR™, Drug Reconstitution and Transfer System has the same intended use as the PhaSeal® closed system for the preparation and administration of parenteral drugs, cleared under 510(k) no. K980381 and has equivalent performance characteristics. It is therefore substantially equivalent to that device.

Conclusion -
The evaluation of the TEVADAPTOR™, Drug Reconstitution and Transfer System does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate devices.

K051669

Indications for Use

510(k) Number (if known): K051669

Device Name: TEVADAPTOR™, Drug Reconstitution and Transfer System

Indications for Use:

The TEVADAPTOR™, Drug Reconstitution and Transfer System is a contained system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs, for intravenous infusion or injection.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051669